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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

NATIONAL INSTITUTE OF FAMILY AND LIFE ADVOCATES on behalf of itself and its members, and SCV PREGNANCY CENTER, Plaintiffs, **v.** **ROB BONTA, in his official capacity as Attorney General of the State of California,** Defendant.	2:24-cv-08468 **ATTORNEY GENERAL ROB BONTA'S OPPOSITION TO PLAINTIFFS' PRELIMINARY INJUNCTION MOTION** Date: December 12, 2024 Time: 10:00 a.m. Courtroom: 5B Judge: Hon. Hernán D. Vera Trial Date: N/A Action Filed: Oct. 2, 2024

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INTRODUCTION

For more than a year, Plaintiffs National Institute of Family and Life Advocates ("NIFLA") and SCV Pregnancy Center ("SCV") (collectively "Plaintiffs") have sat idly by as Defendant Attorney General Rob Bonta ("Attorney General") (sued in his official capacity) has pursued a civil enforcement action to end false and misleading statements in advertisements about so-called "abortion pill reversal" or "APR." And yet, Plaintiffs now claim not only that the Attorney General is infringing their rights, but that—despite their long delay—they are now entitled to preliminary injunctive relief. Specifically, Plaintiffs want to prevent the Attorney General from enforcing California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 et seq. ("UCL"), and False Advertising Law, *id.* § 17500 et seq. ("FAL"), against their own false and misleading statements in APR advertisements and the false and misleading statements of NIFLA's California members. Plaintiffs have not shown the necessary irreparable harm.

Plaintiffs also cannot satisfy the other three preliminary injunction requirements. Because they seek to use false and misleading statements in advertisements, Plaintiffs are not likely to prevail on their claim that the Attorney General is infringing on their free speech right under the First Amendment. Nor do the balance of equities or the public interest support Plaintiffs where they seek to prevent the Attorney General from protecting the public from false and misleading advertisements.

Accordingly, the Court should deny Plaintiffs' motion for preliminary injunction.

FACTUAL BACKGROUND

I. THE MECHANISMS OF MIFEPRISTONE AND PROGESTERONE

Central to this case is the interaction between the first drug in the two-drug medication abortion protocol—mifepristone—and the hormone progesterone. Creinin Decl. ¶¶31-37. The FDA-approved medication abortion protocol requires

two drugs for pregnancy termination: (1) oral administration of 200 mg of mifepristone; and (2) twenty-four to forty-eight hours later, 800 mcg of misoprostol. *Id.* ¶16. The first drug—mifepristone—essentially blocks progesterone from acting on the uterus and the cervix. *Id.* ¶32. Progesterone, which is essential to pregnancy continuation, ensures that the uterus is able to sustain an implanted embryo. *Id.* ¶34. Progesterone does so by binding to progesterone receptors in the uterus and cervix so that both organs are ready for pregnancy. *Id.* ¶¶32-34.

During pregnancy, a massive increase in progesterone floods the body to sustain the pregnancy. *Id.* ¶34. Mifepristone effectively blocks progesterone because the uterus' and cervix's progesterone receptors prefer mifepristone over progesterone, and mifepristone binds more tightly than progesterone. *Id.* ¶32. In other words, the ability to unseat mifepristone from the progesterone receptors requires more than just more progesterone—especially because a pregnant body is already flooded with the hormone. *Id.* ¶¶32, 34-35.

The result of mifepristone's progesterone blocking is that the uterus essentially becomes inhospitable for embryo development, notably by preparing the uterus for contractions to expel its contents. *Id.* ¶32. Misoprostol—the second drug—actually triggers the uterine contractions for which mifepristone has prepared the uterus. *Id.* ¶33. Although the two-drug medication abortion protocol has a high rate of successful pregnancy termination, evidence indicates that the chances of continued pregnancy despite ingestion of the medication increases later in gestation. *Id.* ¶¶14, 22-23.

The rate of continued pregnancy after mifepristone-only administration is a matter of debate because there is little reliable data to establish an accurate baseline. *Id.* ¶36. The studies that do exist are too dissimilar from the current use of mifepristone to be useful. *Id*. In particular, those studies looked at higher doses of mifepristone and with administration during earlier gestations than the current

regimen, thereby potentially suggesting higher rates of pregnancy termination with mifepristone alone than would occur under the current protocol. *Id.* According to at least one review of studies of mifepristone, the rate of continued pregnancy after only-mifepristone administration may range from 8% to 46%. *Id.*; Connolly Decl. Ex. 1.

In short, although reliable scientific studies reveal that mifepristone is very effective at blocking progesterone, there is very little reliable data to establish the rate of continued pregnancy after mifepristone-only administration.

II. DEVELOPMENT OF APR

That current understanding of mifepristone—that it effectively blocks progesterone but may not be very effective at pregnancy termination on its own—is essential context for understanding the logical flaws and inherent unreliability in the so-called studies cited for the APR protocol.

A. 2012 Case Series

Dr. George Delgado, an anti-abortion physician with board certifications in family medicine and hospice and palliative medicine, developed the APR protocol from his theory that increasing the supply of progesterone in the body would "out-compete" mifepristone—despite the pregnant body's already heightened progesterone supply and mifepristone's tighter, more preferred bind with progesterone receptors. Connolly Decl., Ex. 2; Compl. Exs. Y, Z; Creinin Decl. ¶¶35-44. He authored a 2012 case series, published in *The Annals of Pharmacotherapy*, that followed seven women treated with supplemental progesterone after mifepristone administration ("2012 Case Series"). The dosages and routes of administration (i.e., oral capsules, intramuscular injection, vaginal suppository) differed among the six reported cases (with one person lost to follow up), with four live births ultimately occurring. Compl. Ex. Z. As a case series, this article essentially established an area of inquiry for future research, but with its small sample size and confounding variables, the article did nothing more than

suggest further study of the safety and efficacy of the treatment at the population level.[1] Creinin Decl. ¶¶27-28, 44; Connolly Decl., Ex. 3.

Nevertheless, Delgado laid out a protocol: that supplemental progesterone should be administered intramuscularly in regular intervals throughout the first trimester.[2] Compl. Ex. Z. He also established a hotline to connect individuals who had started a medication abortion but wanted to maintain a pregnancy with providers willing to prescribe supplemental progesterone. Compl. Ex. Y.

B. 2017 Literature Review

In 2017, Delgado and his 2012 Case Series co-author, Dr. Mary Davenport, conducted a "literature review" purporting to establish the baseline of pregnancy continuation following administration of mifepristone without misoprostol. Compl. Ex. S. This baseline is essential to establishing whether pregnancy continuation after APR is the result of supplemental progesterone or just mifepristone's limited effectiveness at pregnancy termination absent subsequent administration of misoprostol. *Id.*; Creinin Decl. ¶¶36, 45.

Relying on sixteen early studies of mifepristone that largely featured higher dosages and earlier gestations than the current regimen—which, as explained above, would likely skew the results to show mifepristone was more effective on its own at pregnancy termination—Davenport nevertheless concluded that an appropriate baseline rate of pregnancy continuation after a single 200 mg dose of

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[1] The Turner and Raymond articles that Dr. Bane references fail to offer any greater support for APR. Bane Decl. ¶¶63, 66. The Turner article consists of two small case series of three and six individuals, thereby providing only a small data set from which to derive any conclusions. *Id.* ¶63; Creinin Decl. ¶49. And the Raymond article addressed administration of progesterone-based contraception simultaneously with mifepristone with the goal of preventing future pregnancy at the same time as termination. Bane Decl. ¶66; Creinin Decl. ¶50.

[2] Notably, mifepristone begins to rapidly leave the body within 72 hours of ingestion and is undetectable after ten days. Compl. Ex. Y; Connolly Decl., Ex. 1. There is no explanation in any of Delgado's research why supplemental progesterone is necessary through the entire first trimester of pregnancy.

mifepristone was less than 25%. Compl. Ex. S. But even in the studies Davenport included, rates of pregnancy continuation after just mifepristone administration ranged from 0% to 50%. Compl. Ex. S. In short, Davenport's conclusion that mifepristone administration alone causes more than 75% of pregnancies to end is clearly unsupported.

C. 2018 Report

Delgado and Davenport nevertheless used Davenport's unreliable baseline in a 2018 article purporting to establish the effectiveness of APR. Compl. Ex. Y. Using patient data gathered from his hotline, Delgado engaged in a "retrospective analysis" of 547 patients who had taken supplemental progesterone within 72 hours of mifepristone administration and had maintained pregnancies until 20 weeks ("2018 Report").[3] *Id.* The 2018 Report, published in the journal *Issues in Law and Medicine*, included a variety of supplemental progesterone dosages, methods of administration, and gestational ages, with 325 different medical professionals actually treating the patients. *Id*. The report noted that practitioners used ultrasounds to establish an ongoing pregnancy prior to providing supplemental progesterone. *Id.* The report identified this practice as a "confounding variable" that may have biased the results toward pregnancies that were likely to continue anyway after mifepristone administration—even absent supplemental progesterone.

Delgado nevertheless concluded that the overall rate of pregnancy continuation after any form of supplemental progesterone administration was 48%. Compl. Ex. Y. With Davenport's problematic baseline of 25% pregnancy continuation after mifepristone administration, Delgado declared that the 48% rate of pregnancy continuation was the result of supplemental progesterone. Compl. Ex.

[3] The analysis started with 754 patients, but excluded 207 for three reasons: 1) more than 72 hours had elapsed between mifepristone administration and supplemental progesterone administration (38 patients); 2) loss of contact with the patient before 20 weeks gestation (112 patients); and 3) patient chose to complete abortion (57 patients). Compl. Ex. Y.

Y. No clinical data support this conclusion. Furthermore, the 2018 Report offered no results on *maternal* health outcomes, only on pregnancy continuation and rate of birth defects. Compl. Ex. Y.

Despite the limitations of a retrospective analysis, which is not a reliable basis for determining safety or effectiveness of medical treatments, Creinin Decl. ¶¶44-48, Delgado offered new protocols for supplemental progesterone. Looking to the 31 patients who received high doses of oral progesterone and the 125 patients who received intramuscular progesterone injections, Delgado proposed: 1) 200 mg of oral progesterone at regular intervals throughout the first trimester; or 2) 200 mg of intramuscular progesterone injections for at least seven injections. Compl. Ex. Y.

D. 2019 U.C. Davis Medical School Study

In 2019, Dr. Mitchell Creinin, a professor and researcher in the Department of Obstetrics and Gynecology at the U.C. Davis Medical School, sought to test the APR theory through a randomized controlled trial, which is the best form of scientific evidence. Creinin Decl. ¶¶4-6, 29, 57-61. The plan was to enroll forty patients at 44-63 days of gestation who intended to terminate their pregnancies and who all had embryos with cardiac activity. *Id.* ¶58. These patients would receive 200 mg of mifepristone, followed twenty-four hours later by either a placebo or 400 mg of oral progesterone at regular intervals until either a complete abortion or a planned surgical abortion. *Id.* But, Creinin had to stop the study after enrollment of only twelve patients after two patients dropped out because of their symptoms, and three of the remaining ten patients experienced severe hemorrhaging necessitating emergency ambulance transport to the hospital. *Id.* ¶¶59-61. Of the three who experienced hemorrhaging, one had received progesterone and had a completed abortion; and two had received the placebo, with both requiring surgical abortions. *Id.* ¶59.

Due to small sample size and early termination of the study, Creinin was unable to show whether supplemental progesterone could be effective at preventing

abortion after mifepristone administration. *Id.* ¶¶59-61. The study did suggest, however, that there are safety risks associated with APR, particularly for the individuals whose pregnancies do not continue. *Id.*

III. CRITICISMS OF APR

In light of the significant flaws in the evidence cited to support APR, it has been the subject of significant criticism. *See, e.g.*, Connolly Decl., Ex. 1 208 (2012 Case Series was "of poor quality with few details"); *Id.*, Ex. 4 1493 ("[A]ny use of reversal treatment should be considered experimental.").

The American College of Obstetricians and Gynecologists has stated that "[c]laims regarding abortion 'reversal' treatment are not based on science and do not meet clinical standards." Connolly Decl., Ex. 5. The Society of Obstetricians and Gynaecologists of Canada has stated that "[t]he claims regarding so-called abortion 'reversal' treatments are not based on scientific evidence." *Id.*, Ex. 6. The Royal College of Obstetricians and Gynaecologists, the Faculty of Sexual and Reproductive Healthcare, the Royal College of Midwives, and the British Society of Abortion Care Providers have stated that "[t]here are no reputable national or international clinical guidelines that recommend the use of progesterone to reverse the effect of mifepristone, and no evidence that it increases the likelihood of continuing pregnancy, compared to expectant management alone." *Id.*, Ex. 7.

Even in the National Institute for Health and Care Excellence ("NICE") reports that Plaintiffs offer in support, NICE was explicit that supplemental progesterone was not recommended after the administration of mifepristone. *See* Compl. Ex. O 33 ("The recommendations are not applicable in other circumstances, such as after the use of mifepristone."); *Id.* Ex. P 20 (NICE was "not aware of any evidence that the use of progesterone would be safe and effective" in APR.).

The lack of scientific data supporting APR was also the subject of three lawsuits challenging state legislation mandating that abortion providers tell patients that medication abortion could be "reversed," with the federal district courts

determining in each case that there was insufficient evidence to support that APR was effective. *Planned Parenthood of Tenn. & N. Miss. v. Slatery*, 523 F. Supp. 3d 985, 989 (M.D. Tenn. 2021); *All-Options, Inc. v. Atty. Gen. of Ind.*, 546 F. Supp. 3d 754, 766-68 (D. Ind. 2021); *Am. Med. Ass'n v. Stenehjem*, 412 F. Supp. 3d 1134, 1150 (D.N.D. 2019); *see also* Atty. Gen. Rob Bonta's Req. for J. Not. ("RJN"), Exs. 4-14.

In all three cases, the courts enjoined the legislation because the mandatory disclosures were false and misleading due to the lack of reliable scientific evidence underlying APR. *See Slatery*, 523 F. Supp. 3d at 989 ("the mandated 'reversal' message is misleading because it suggests progesterone therapy has reached a level of safety and efficacy that is not supported by medical evidence"); *All-Options, Inc.*, 546 F. Supp. 3d at 766-68 (APR "medical studies, testimony about biological principles, and physicians' clinical experiences…do[] not establish causation"); *Stenehjem*, 412 F. Supp. 3d at 1150-51 (APR is "unproven medical and scientific theory" and "devoid of credible scientific evidence").

IV. THE ATTORNEY GENERAL'S APR ENFORCEMENT ACTION

Heartbeat International, Inc. ("HBI") operates the Abortion Pill Rescue Network ("APRN"), as well as the website and hotline that grew out of Delgado's hotline. Compl. Ex. VV; RJN Ex. 1 ¶49; Connolly Decl. Ex. 8. Through that website and hotline, as well as through materials provided to potential patients and through public appearances, HBI advertises APR, including through the use of specific statements that are false and misleading because they lack any credible evidence, including: (1) the use of the terms "reverse" or "reversal"; (2) that APR "has been shown to increase the chances of allowing the pregnancy to continue"; (3) that APR has a success rate of 64-68%; (4) that the rate of birth defects following APR "is less or equal to the rate in the general population"; (5) that "thousands of lives have been saved" through APR; (6) that APR may be effective beyond a 72-hour window following mifepristone administration; (7) that APR may

be effective following administration of misoprostol and methotrexate; and (8) that APR can cause only non-life-threatening side effects, when in fact APR can cause severe, life-threatening bleeding. Connolly Decl. Exs. 8-9; Compl. Ex. C ¶¶97, 100. HBI also aids and abets false advertising by providing training kits to CPCs and medical providers that encourages the use of these false and misleading statements in their APR advertisements. Compl. Ex. C ¶¶71-81.

RealOptions, which operates five licensed community clinics in California, similarly advertises APR as a service that it provides, and similarly uses statements that are false and misleading because they lack any credible supporting evidence: (1) the use of the terms "reverse" or "reversal"; (2) that APR "has been shown to increase the chances of allowing the pregnancy to continue"; (3) that APR has a success rate of 64-68%; and (4) that APR can cause only non-life-threatening side effects, when in fact APR can cause severe, life-threatening bleeding.[4] Compl. Ex. WW; *Id.* Ex. C ¶¶97, 100.

To protect California residents, on September 21, 2023, the Attorney General filed a civil enforcement action ("Enforcement Action") in Alameda County Superior Court alleging violations under the UCL and FAL. Compl. Ex. C. HBI and RealOptions demurred to the complaint, which the state court overruled in June 2024.[5] RJN Ex. 2. The case is now in discovery, with a trial date set for November 3, 2025. RJN Ex. 3

V. PLAINTIFFS' INTENDED APR ADVERTISEMENTS

SCV, NIFLA, and NIFLA's members want to advertise APR through use of the terms "reverse" and "reversal" and through statements that APR is "safe" and "effective." Compl. ¶42 ("California NIFLA members have canceled or postponed

[4] To the extent RealOptions is a NIFLA member, abstention under *Younger v. Harris* is warranted. 401 U.S. 37 (1971); *Middlesex Cnty. Ethics Comm. v. Garden State Bar Ass'n*, 457 U.S. 423, 431 (1982).

[5] The state court also denied HBI's motion to quash the summons on grounds of lack of personal jurisdiction.

plans to advertise about APR options"); *id.* ¶47 (NIFLA's associational standing based on "California members" who want to "to advertise…about progesterone treatment"); *id.* ¶63 (SCV's statements about APR "were identical to or nearly identical to" or "substantially similar to" HBI and RealOptions statements); *id.* ¶195 (PCC "paid for an advertisement campaign" about APR); *see also id.* ¶¶39-41, 43-45, 194, 201-204, 207, 209, 235-241, 246.

NIFLA member Pregnancy Care Clinic ("PCC") "paid for an advertising campaign informing women about [APR]," including bus bench advertisements referring patients to HBI's abortionpillreversal.com website. Compl. Ex. CC ¶¶13-14; *see also id.* ¶17-18; Connolly Decl. Ex. 10. NIFLA member Alternatives Pregnancy Center ("APC") advertises on its website that it provides "abortion pill reversal." Connolly Decl. Ex. 11; *see also* Compl. Ex. DD ¶5. And Plaintiff SCV has posted advertisements for APR on its social media account, stating "Can the abortion pill be reversed? The simple answer is yes!" and referring potential patients to HBI's hotline. Compl. Ex. FF; *see also* Compl. Exs. GG, HH, II.

For its part, NIFLA wants to aid and advise its members on advertising APR. Compl. ¶213 (NIFLA "published informational guides about [APR]…regularly consulted with centers regarding [APR], and provided sample policies that encouraged its members to speak about [APR] and to provide it as one of their services"); *id.* ¶221 (NIFLA previously "advis[ed] its California centers to advertise for" APR); *see also id.* ¶211-212, 214, 216-218, 223-224.

In its guidance to its centers, NIFLA recommends HBI's APR training program (Compl. Ex. EE), which in turn instructs medical providers to offer the false and misleading statements identified above in their advertisements to patients to undergo APR. Connolly Decl. Ex. 12 14-17 (false advertisement that APR has 64-68% success rate, that "it may not be too late" after 72 hours); *id.* Ex. 12 23-24 (APR for people who have taken methotrexate); *id.* Ex. 12 27-28 (APR for people who have taken mifepristone and misoprostol).

VI. PLAINTIFFS' FINANCIAL EARNINGS

NIFLA's annual revenue for 2022 was $1,251,805, which consisted of $368,151 in membership dues; $528,273 from the provision of training and materials; and $355,381 in "all other contributions, gifts, grants and similar amounts." Connolly Decl. Ex. 13 1, 9; *see also id.* Exs. 14-15 (2020-2021 NIFLA revenue). APC had $1,899,205 in total revenue for 2022, which consisted of $1,590,416 in contributions and grants and $305,321 in "other revenue" and included revenue from fundraisers. Connolly Decl. 16 1, 9; *see id.* Exs. 17-18 (2019, 2021 APC revenue). PCC had $760,510 in total revenue in 2022, which consisted of $466,813 in contributions and grants; $13,944 in investment income; and $279,753 in "other revenue" and included revenue from fundraisers. Connolly Decl. 19 1, 9; *see id.* Exs. 20-21 (2020-2021 PCC revenue).

SCV, for its part, had $781,839 in revenue in 2022, which consisted of $588,319 in contributions and grants; $6,301 in service revenue, such as clinic services; and $187,219 in "other revenue." Connolly Decl. Ex. 22; *see also id.* Exs. 23-24 (2019, 2021 SCV revenue). SCV has billed Medi-Cal for its patients, including 24 of its 406 patients in 2021; 32 of 457 patients in 2020; and 95 of 495 patients in 2019. Connolly Decl. Exs. 25-27.

LEGAL STANDARD

"A preliminary injunction is an extraordinary remedy never awarded as of right," *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008), and "should not be granted unless the movant, by a clear showing, carries the burden of persuasion," *Lopez v. Brewer*, 680 F.3d 1068, 1072 (9th Cir. 2012). Plaintiffs "must establish" four elements: (1) that they are "likely to suffer irreparable harm in the absence of preliminary relief"; (2) that they are "likely to succeed on the merits"; (3) that "the balance of equities tip[] in [their] favor"; and (4) that "an injunction is in the public interest." *Winter*, 555 U.S. at 20. Courts "should pay

particular regard for the public consequences in employing the extraordinary remedy of injunction." *Id.* at 24 (quotation omitted).

ARGUMENT

I. PLAINTIFFS HAVE NOT AND CANNOT SHOW IRREPARABLE HARM

Plaintiffs' year-plus delay in seeking a preliminary injunction undercuts their claims of needing immediate relief. "A preliminary injunction is sought upon the theory that there is an urgent need for speedy action to protect the plaintiff's rights," but "[b]y sleeping on its rights a plaintiff demonstrates the lack of need for speedy action." *Lydo Enter., Inc. v. City of Las Vegas*, 745 F.2d 1211, 1213 (9th Cir. 1984) (quotations omitted); *see also Garcia v. Google, Inc.*, 786 F.3d 733, 746 (9th Cir. 2015) (delay of "months" "undercut" plaintiff's "claim of irreparable harm").

On September 21, 2023—more than a year before this motion—the Attorney General filed and announced the Enforcement Action via press release and press conference. Compl. Exs. C, OO, PP. Plaintiffs' own evidence reveals knowledge of the Enforcement Action shortly after its filing. Compl. ¶204. Nor is it credible for NIFLA to disclaim knowledge of the Enforcement Action shortly after it was filed, given that NIFLA's mission is to "equip[]" CPCs "with legal resources, counsel, education, training, and support." Compl. ¶30. Plaintiffs' long delay in seeking relief shows preliminary injunctive relief is unwarranted.

II. PLAINTIFFS HAVE NOT AND CANNOT SHOW A LIKELIHOOD OF SUCCESS ON THE MERITS

A. The First Amendment Does Not Protect Plaintiffs' False and Misleading Statements in Advertisements About APR

Plaintiffs cannot show likelihood of success on the merits of their claim that the Attorney General is infringing their free speech rights under the First Amendment.[6] Plaintiffs seek to use false and misleading statements in their

[6] Plaintiffs have sought this injunction only on grounds that the Enforcement Action violates their free speech rights under the First Amendment. Prelim. Inj. Mot. 2 (Enforcement Action "chills Plaintiffs' constitutionally protected speech"; (continued…)

advertisements about APR. As such, the First Amendment does not protect their speech.[7] *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 563 (1980) ("[T]here can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity."). Accordingly, Plaintiffs cannot show a likelihood of success on the merits.

1. Plaintiffs' Proposed APR Statements Are Commercial Speech

Plaintiffs are explicit that they want to advertise APR using statements that APR can "reverse" medication abortion and that APR is "safe" and "effective." Compl. ¶¶13, 39-45, 47, 63, 194, 201-204, 207, 209, 235-241, 246. Plaintiffs nevertheless argue that their intended speech is not commercial because—they claim—they do not receive any payment as a result of their APR advertisements.

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irreparable harm is "the continued violation of their rights to free speech guaranteed by the Constitution"); Prelim. Inj. Mem. Pts. & Auth. ("MP&A") 9-19 (arguing exclusively about chill to speech rights). Accordingly, Plaintiffs have waived any recourse to their Free Exercise or Due Process Clause claims. *Zamani v. Carnes*, 491 F.3d 990, 997 (9th Cir. 2007) ("The district court need not consider arguments raised for the first time in a reply brief."). To the extent Plaintiffs turn to their Free Exercise or Due Process Clause claims in their reply, the Attorney General reserves the right to file a sur-reply to address those arguments. *El Pollo Loco, Inc. v. Hashim*, 316 F.3d 1032, 1040-41 (9th Cir. 2003) (courts may consider "new evidence presented in a reply brief if the district court gives the adverse party an opportunity to respond").

[7] Nor can Plaintiffs point to statements not in advertisements because they would lack pre-enforcement standing by failing to establish either that their conduct is "proscribed by a statute" or that there is a "credible threat of prosecution." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014). The Attorney General is prosecuting HBI and RealOptions only for the false and misleading statements made in their advertisements for APR, not for APR speech writ large. Compl. Ex. C ¶¶97, 100. And the UCL and FAL only prohibit speech that qualifies as an "advertisement" or "fraudulent representation." *See* Cal. Bus. & Prof. Code § 17200 ("fraudulent business act[s] or practice[s]" prohibited); *Id.* § 17500 ("untrue or misleading" statements to "induce public to enter into any obligation relating thereto" prohibited).

Prelim. Inj. MP&A 12:14-20, 13:1-12. But Plaintiffs too narrowly construe the kind of speech that qualifies as "commercial" under the First Amendment.

Although "[c]ommercial speech is usually defined as speech that does no more than propose a commercial transaction," "[c]ourts view this definition as just a starting point…and instead try to give effect to a common-sense distinction between commercial speech and other varieties of speech." *Ariix, LLC v. NutriSearch Corp.*, 985 F.3d 1107, 1115 (9th Cir. 2021) (quotations omitted). The "'commercial speech analysis is fact-driven, due to the inherent difficulty of drawing bright lines that will clearly cabin commercial speech in a distinct category.'" *Id.* (quoting *First Resort, Inc. v. Herrera*, 860 F.3d 1263, 1272 (9th Cir. 2017)).

"'Where the facts present a close question, strong support that the speech should be characterized as commercial speech is found where [1] the speech is an advertisement, [2] the speech refers to a particular product, and [3] the speaker has an economic motivation.'" *Id.* (quoting *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 64-67 (1983)). "These so-called *Bolger* factors are important guideposts, but they are not dispositive." *Id.*; *see also Bolger*, 463 U.S. at 67 n.14 ("Nor do we mean to suggest that each of the characteristics present in this case must necessarily be present in order for speech to be commercial.").

Plaintiffs' past and proposed future speech about APR falls well within the boundaries of commercial speech. First, Plaintiffs want to advertise APR (and in the case of NIFLA, aid and abet in the advertisement of APR), thereby satisfying the first two *Bolger* factors. *See, e.g.*, Compl. ¶42 ("California NIFLA members have canceled or postponed plans to advertise about APR options"); *id.* ¶47 (NIFLA's "California members" want "to advertise…about progesterone treatment"); *id.* ¶195 (PCC "paid for an advertisement campaign" about APR); *id.* ¶221 (NIFLA previously "advis[ed] its California centers to advertise for" APR); Compl. Ex. CC ¶¶13-14 (PCC "paid for an advertising campaign informing women

about" APR); Compl. Ex. FF (SCV APR advertisement: "Can the abortion pill be reversed? The simple answer is yes!" with referral to HBI's hotline). And patients who undergo APR may have to pay for—or have insurance cover—their supplemental progesterone prescription. Connolly Decl. Ex. 12 13, 16.

On these grounds alone, Plaintiffs' speech qualifies as commercial. "[T]he potential commercial nature of speech does not hinge solely on whether [a plaintiff has] an economic motive, as even *Bolger* does not preclude classification of speech as commercial in the absence of the speaker's economic motivation." *First Resort*, 860 F.3d at 1273 (quotations omitted).[8] Here, Plaintiffs' APR advertisements are "placed in a commercial context and are directed at the providing of services rather than toward an exchange of ideas." *Id.* at 1276 (quotations omitted). As such, their speech qualifies as commercial, regardless of their economic motivation.

Plaintiffs, however, have economic motivations for their APR advertisements.[9] NIFLA, for example, earns a majority of its annual revenue from the combination of the membership dues its crisis pregnancy center ("CPC") affiliates pay and payments it receives for training and materials. Connolly Decl. Exs. 13-15. In exchange for these fees, NIFLA "equip[s]" its CPCs "with legal resources, counsel, education, training and support," Compl. ¶30, including about APR, *id.* ¶224. *See also id.* ¶¶45, 50, 182, 208-230. For its part, SCV bills to Medi-Cal for at least a portion of its patients, which could include the patients to whom it intends to

[8] Plaintiffs' claim that *First Resort* is wrongly decided, Prelim. Inj. MP&A 12:24-26, is meritless. Not only did the Ninth Circuit recently cite *First Resort* approvingly, *Ariix, LLC*, 985 F.3d at 1115, but *First Resort* does nothing more than apply *Bolger*, which does not require economic motivation for speech to be commercial. *Bolger*, 463 U.S. at 67 n.14.

[9] NIFLA, SCV, and NIFLA members APC and PCC also derive a significant proportion of their revenue from contributions and fundraising. Connolly Decl. Exs. 16-21 (Form 990s showing sources of revenue). Although at this preliminary stage the Attorney General has not had an opportunity to conduct discovery, such fundraising activities may be further economic motivation. *See First Resort*, 860 F.3d at 1273.

provide APR. Compl. ¶247; Connolly Decl. Exs. 22-27. With this evidence of economic motivation, Plaintiffs' speech satisfies all three *Bolger* factors and thereby easily qualifies as commercial speech.

2. Statements that APR Can "Reverse" Medication Abortion or that APR Is Safe and Effective Are False and Misleading

Because Plaintiffs' speech qualifies as commercial, false and misleading statements as part of that speech have no First Amendment protection. "The government may ban forms of communication more likely to deceive the public than to inform it." *Cent. Hudson*, 447 U.S. at 563; *see also Enigma Software Grp. USA, LLC v. Malwarebytes, Inc.*, 69 F.4th 665, 674 (9th Cir. 2023) ("misleading statements of fact" for "commercial advantage" are "offensive" and "actionable").

Plaintiffs have used and want to continue to use in their APR advertisements statements that APR "reverses" medication abortion and is "safe" and "effective." *See supra* Section II.A.1. Because there is no scientific basis for any of these claims, each of the statements is false and misleading and, when used as part of their APR advertisements, has no First Amendment protection.

"Reverse" and "Reversal" Are False and Misleading: As explained above, mifepristone binds preferentially and more tightly to progesterone receptors in the uterus and cervix than progesterone, and in so doing not only prevents the uterus and cervix from preparing for implantation but actually prepares them to expel tissue. Creinin Decl. ¶32. Under APR proponents' theory, supplemental progesterone can "outcompete" mifepristone through sufficiently high concentrations in relation to the mifepristone, such that the supplemental progesterone will bind to the receptors instead. *See* Bane Decl. ¶31.[10] This theory fails to account for the fact that mifepristone binds preferentially or more tightly to

[10] As reflected in the Attorney General's objection to Dr. Bane's declaration, she is not qualified to be an expert on the subject of APR or mifepristone. *See* Atty. Gen. Rob Bonta's Obj. to Pls. Evid. ISO Prelim. Inj. Mot.

the receptors. And that failure matters, because no evidence suggests that higher concentrations of progesterone can unseat mifepristone from the receptors—i.e., "reverse" the mifepristone. Creinin Decl. ¶¶32-35. Indeed, "the word 'reverse' does not accurately describe to patients the medical research on progesterone therapy." *Slatery*, 523 F. Supp. 3d at 1002.; *see also* Creinin Decl. ¶¶37-39.

Plaintiffs no doubt want to continue using the terms "reverse" and "reversal" exactly because those terms are ones that individuals who are considering stopping a medication abortion would include in their online searches. *See* Compl. Exs. A, B. But that is why Plaintiffs' use of the terms is so misleading—"reverse" and "reversal" promise something Plaintiffs' own theory of APR does not deliver.

***Statements that APR Is "Safe" Are False and Misleading*:** None of the evidence that Plaintiffs offer supports that APR is safe. The 2018 Report, notably, did not track safety outcomes for the individuals who underwent APR and did not mention any outcomes at all for the individuals whose pregnancies did not continue. Compl. Ex. Z. The 2012 Case Series, following six individuals, is far too small to establish that the APR protocol is safe. Creinin Decl. ¶¶43-44. In fact, the 2019 U.C. Davis study, which included three individuals who had significant bleeding after ingesting mifepristone without subsequent misoprostol, undermines any support that the 2012 Case Series might provide that APR is safe. *Id.* ¶¶59-61; Connolly Decl. Ex. 28.

Plaintiffs offer studies showing that supplemental progesterone, alone, is safe during pregnancy, but those studies are irrelevant to whether APR—which requires administration of mifepristone, administration of supplemental progesterone, and a lack of administration of misoprostol—is safe. Prelim. Inj. MP&A 10:16-19; Compl. Exs. O, BB; Bane Decl. ¶37. They say nothing about whether supplemental progesterone interacts positively or negatively with mifepristone, or whether administration of mifepristone without misoprostol (an APR prerequisite) is safe.

In short, the studies establish only that supplemental progesterone, by itself, may be safe during pregnancy.

Finally, although supplemental progesterone during pregnancy is low risk, it is not zero risk. Creinin Decl. ¶¶62-66. The rare risks associated with supplemental progesterone are tolerable in situations where the medication has actual benefits. *Id.* But, as described below, there is no support for Plaintiffs' claim that supplemental progesterone is effective at continuing a pregnancy after mifepristone administration. In such circumstances, even the low risk from supplemental progesterone is not justified. *Id.*

In sum, Plaintiffs have not established that APR is safe.

***Statements that APR Is "Effective" Are False and Misleading*:** None of Plaintiffs' evidence shows that APR is effective. The crux of their evidence is the 2018 Report, a "retrospective analysis" of treatments by 325 different medical professionals using a variety of administrations and dosages of progesterone on individuals at a variety of gestational ages. Compl. Ex. Y. The 2018 Report, however, is so flawed that it does not and cannot establish that APR is effective.[11] Creinin Decl. ¶45.

First, the report's baseline rate of 25% for continuing pregnancies following mifepristone administration is likely artificially low (thus artificially boosting supplemental progesterone's effectiveness rate), given that other studies suggest a rate ranging between 8% and 46%. *Id.* ¶¶36, 45. Second, as the report acknowledges, some (unknown) number of the patients received an ultrasound establishing embryo/fetal cardiac activity before receiving supplemental progesterone, thereby biasing the patient population toward pregnancies likely to continue after mifepristone-only administration. Compl. Ex. Y. Third, the report

[11] Nor is a "retrospective analysis" the type of evidence from which medicine makes safety and efficacy determinations for treatment protocols, even in the absence of these methodological flaws. Creinin Decl. ¶44.

does not connect gestational age to route of progesterone administration or dosage, which is problematic in light of mifepristone's waning effectiveness at terminating pregnancies at later gestational ages. Compl. Ex. Y; Creinin Decl. ¶45. Fourth, as a "retrospective analysis" of care via 325 different medical providers, there are no controls to establish that supplemental progesterone "caused" pregnancies to continue. In short, the 2018 Report offers nothing more than anecdotal data, rather than the rigorous scientific study necessary to establish causation. Creinin Decl. ¶45.

Nor can Plaintiffs rely on animal studies or small case studies like the 2012 Case Series. Animal studies can suggest areas of future research, but they cannot establish that a particular medical protocol works in humans. *Id.* ¶¶30, 51-55. Small case series like the 2012 Case Series likewise provide only areas for future investigation due to the small number of patients involved, the lack of controls, and the likelihood of bias influencing the results. *Id.* ¶¶27-28, 44, 49; Connolly Decl. Ex. 3. In sum, none of the evidence Plaintiffs offer supports that APR is "effective."

Because there is no support for Plaintiffs' statements that APR is "safe," or "effective," or that APR "reverses" mifepristone, each of these statements is false and misleading, and to the extent they appear in Plaintiffs' APR advertisements, they receive no First Amendment protection.

B. Plaintiffs' Challenges to the UCL and FAL Are Meritless

Plaintiffs next turn to a broad attack on the UCL and FAL statutes themselves—asserting that they violate the First Amendment. *See* Prelim. Inj. MP&A 13:20-14:6. As a threshold matter, Plaintiffs' proposed speech has no First Amendment protection and therefore the UCL and FAL's compliance with the First Amendment is irrelevant. *Cent. Hudson*, 447 U.S. at 566 ("For commercial speech to come within [the First Amendment], it at least must concern lawful activity and not be misleading."); *Edenfield v. Fane*, 507 U.S. 761, 768 (1993) ("[T]he State

may ban commercial expression that is fraudulent or deceptive without further justification."). But regardless, the argument is meritless.

Plaintiffs claim that "[t]he First Amendment does not allow the Attorney General to silence what he considers 'false and misleading speech without showing that anyone has been harmed by those statements." Prelim. Inj. MP&A 13:20-22. Plaintiffs also claim that the Attorney General must show that they receive a "material benefit" from their speech. Prelim. Inj. MP&A 14:14-15. In support, Plaintiffs rely on *United States v. Alvarez*, in which a Supreme Court plurality "reject[ed] the notion that false speech should be in a general category that is presumptively unprotected" by the First Amendment. 567 U.S. 709, 722 (2012). But nowhere in its decision did the *Alvarez* plurality suggest—let alone state—that government enforcement actions for consumer fraud must identify harmed individuals or material benefits to the perpetrators. Instead, the *Alvarez* plurality explicitly identified "fraud" as a category of speech that has a "historical foundation in the Court's free speech tradition." 567 U.S. at 717-18; *see also Illinois, ex rel. Madigan v. Telemarketing Assocs., Inc.*, 538 U.S. 600, 612 (2003) ("*Madigan*") ("[T]he First Amendment does not shield fraud."). And a UCL/FAL enforcement action requires that the Attorney General show that the statements at issue are either advertisements, Cal. Bus. & Prof. Code § 17500, or "fraudulent business act[s] or practice[s]," *id.* § 17200, not just false statements writ large. *Alvarez* is inapplicable.

Plaintiffs' other case in support, *Madigan*, is also inapposite. There, the Supreme Court addressed the First Amendment's application in the specific context of a fraud action brought against an organization soliciting charitable donations through affirmative misrepresentations. 538 U.S. at 618-19. Critical to the Court's decision was the context of its three earlier decisions prohibiting "prophylactic measures" to prevent fraud in the context of solicitations for charitable donations that included prior restraints on speech. *Id.* at 612-17. In light of that context, the

Court concluded that the Illinois Attorney General's enforcement action, which "target[ed] misleading affirmative representations," satisfied the First Amendment. *Id.* at 619. Notably absent from the decision are the requirements Plaintiffs seek to impose.[12] Thus, Plaintiffs' challenge to the UCL and FAL fall short.

C. Plaintiffs' Claim that the Attorney General's UCL/FAL Enforcement is Viewpoint Discriminatory Is Meritless

There is likewise no merit to Plaintiffs' claim that the Attorney General is enforcing the UCL and FAL in a viewpoint-discriminatory manner. Prelim. Inj. MP&A 17:6-19:24. Contrary to Plaintiffs' claims, they are not "similarly situated" to Planned Parenthood. Planned Parenthood's statements about medication abortion are supported by decades of rigorous medical research that establish the safety and efficacy of the two-drug protocol that the FDA has approved. Creinin Decl. ¶¶14-25. In fact, in 2016, the FDA loosened restrictions on mifepristone because data from the fifteen prior years had established that complications were rare and that the drug was safe. *Id.* ¶¶15-17. In contrast, Plaintiffs' statements about APR have no basis in scientific evidence and are not supported even by the articles they cite. *See supra* Section II.A.2. As such, the Attorney General is well within the exercise of his prosecutorial discretion by bringing an enforcement action against false and misleading APR advertisements, while not prosecuting Planned Parenthood's accurate statements about APR and medication abortion.

In sum, Plaintiffs have not and cannot show that they are likely to prevail on their claims that the Attorney General is violating or will violate their Free Speech Clause rights. Because this factor is a "threshold inquiry" and "the most important factor," the Court "need not consider the other factors if a movant fails to show a likelihood of success on the merits." *Baird v. Bonta*, 81 F.4th 1036, 1040 (9th Cir.

[12] NIFLA, at least, has likely known since at least 2019 about the utter lack of scientific support for APR. RJN Ex. 14 (2019 NIFLA intervention motion in *Stenehjem*).

2023) (quotations omitted). Accordingly, on this factor alone, the Court should deny Plaintiffs' request for preliminary injunctive relief.

III. PLAINTIFFS HAVE NOT AND CANNOT SHOW THAT THE BALANCE OF EQUITIES AND THE PUBLIC INTEREST SUPPORT A PRELIMINARY INJUNCTION

"When the government is a party," the balance of equities and public interest "factors merge." *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). "[A]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, J., in chambers) (quotations omitted). Here, the balance of equities and the public interest tip sharply in favor of the Attorney General who would, if Plaintiffs are successful, be unable to protect the public against false and misleading statements in advertisements for a medical procedure. *Cf. Pearson v. Shalala*, 164 F.3d 650, 656 (9th Cir. 1999) ("[T]he government's interest in preventing consumer fraud/confusion may well take on added importance in the context of a product…that can affect the public's health."). Accordingly, these factors also weigh against issuing preliminary injunctive relief.

CONCLUSION

None of the *Winter* factors support Plaintiffs' request for a preliminary injunction. The Court should deny Plaintiffs' motion.

Dated: November 4, 2024

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CERTIFICATE OF COMPLIANCE

The undersigned, counsel of record for Attorney General Rob Bonta, sued in his official capacity, certifies that this brief contains 6,929 words, which:

X complies with the word limit of L.R. 11-6.1.

__ complies with the word limit set by court order.

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